

Pursuant to Federal Rule of Civil Procedure 6, the parties file this joint motion to extend deadlines.

2. Pursuant to the Court's February 7, 2022 Order (ECF No. 17), NPA filed its First Amended Complaint on February 21, 2022 (ECF No. 19).

4. On March 31, 2022, FDA responded to the first request in NPA's citizen petition.

5. To provide NPA time to evaluate FDA's citizen petition response and determine whether to file a second amended complaint, on April 7, 2022, the parties filed a joint motion regarding certain deadlines in this case (ECF No. 26), which the Court granted on April 8, 2022 (ECF No. 27).

6. On April 22, 2022, FDA published notice in the Federal Register of a draft guidance titled, "Policy Regarding N-acetyl-L-cystine: Guidance for Industry." *See* Notice of Availability, 87 Fed. Reg. 24170 (Apr. 22, 2022). The notice instructed the public to submit comments on the draft guidance by May 23, 2022, to ensure that FDA considers the comments before working on the final version of the guidance.

7. To provide NPA time to review FDA's final guidance, once issued, on May 19, 2022, the parties jointly moved this Court to extend certain deadlines in this case (ECF No. 30). The Court granted that motion (ECF No. 31), and ordered the following:

- a. On or before August 10, 2022, NPA will file an unopposed second amended complaint or the parties will file a joint status report.
- b. If NPA files a second amended complaint, Defendants' answer or response will be due within 30 days from the date of service.

8. On August 2, 2022, FDA published notice in the Federal Register of a final guidance titled, "Policy Regarding N-acetyl-L-cystine: Guidance for Industry." *See* 87 Fed. Reg. 47220 (Aug. 2, 2022).

9. On August 10, 2022, the parties submitted a joint status report noting that NPA stated that it needed additional time to review the guidance, and that Defendants did not object to this request. (ECF No. 32). The parties proposed to file a joint status report in 30 days. The Court granted that request. (ECF No. 33). Subsequently, this Court approved the parties' request to set

NPA's deadline for filing an unopposed second amended complaint as October 14, 2022, and Defendants' deadline for filing an answer or response as November 18, 2022. ECF Nos. 34, 35.

11. On October 13, 2022, counsel for NPA emailed counsel for Defendants and requested an extension of time to file their second amended complaint to October 21, 2022 because of counsel's illness. Counsel for Defendants agreed, provided that Defendants' time to answer or respond be extended to December 2, 2022. Counsel for NPA agreed. Accordingly, the parties jointly move that the deadlines be extended as follows:

- a. NPA will file an unopposed second amended complaint by October 21, 2022.
- b. Defendants' will file their answer or response by December 2, 2022.

Dated: October 14, 2022

Respectfully submitted,

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